Proposed Decision Memo for Cardiac Rehabilitation Programs (CAG-00089R)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The evidence is adequate to conclude that cardiac rehabilitation is reasonable and necessary following acute myocardial infarction (AMI), coronary artery bypass graft (CABG), stable angina pectoris, heart valve repair/replacement, percutaneous transluminal coronary angioplasty (PTCA), and heart or heart lung transplant.

CMS has determined that the evidence is not adequate to conclude that cardiac rehabilitation is reasonable and necessary for congestive heart failure, and therefore we will not cover this indication.

CMS proposes revising the language in Manual 100-3 § 20.10 to read as follows:

A – Item/Service Description

Phase II cardiac rehabilitation, as described by the U.S. Public Health Service is a comprehensive, long-term program including medical evaluation, prescribed exercise, cardiac risk factor modification, education and counseling. Phase II refers to outpatient medically supervised programs that are typically initiated 1-3 weeks after hospital discharge and provide appropriate ECG monitoring.

B – Indications and Limitations of Coverage

Medicare coverage of cardiac rehabilitation programs are considered reasonable and necessary only for patients who (1) have a documented diagnosis of acute myocardial infarction within the preceding 12 months; or (2) have had coronary bypass surgery; or (3) have stable angina pectoris; or (4) have had heart valve repair/replacement; or (5) have had percutaneous transluminal coronary angioplasty (PTCA); or (6) have had heart or heart lung transplant.

C – Program Requirements

1. Duration
   Services provided in connection with a cardiac rehabilitation exercise program may be considered reasonable and necessary for up to 36 sessions without individual review by a contractor's medical consultant. Patients generally receive 2 to 3 sessions per week for 12 to 18 weeks. Claims for cardiac rehabilitation services beyond 18 weeks should be reviewed by the contractors' medical consultants to determine if coverage should be extended but not exceed a total of 72 sessions for 36 weeks.

2. Components
   Cardiac rehabilitation programs must be comprehensive and to be comprehensive they must include a medical evaluation, a program to modify cardiac risk factors (e.g., nutritional counseling), prescribed exercise, education and counseling.

3. Facility
   The facility must have available for immediate use the necessary cardio-pulmonary emergency diagnostic and therapeutic life saving equipment accepted by the medical community as medically necessary, e.g., oxygen, cardiopulmonary resuscitation equipment, or defibrillator.

4. Staff
   The program must be staffed by personnel necessary to conduct the program safely and effectively, who are trained in both basic and advanced life support techniques and in exercise therapy for coronary disease. The program must be under the direct supervision of a physician, as defined in 42 C.F.R. § 410.26(a)(2) (defined through cross reference to 42 C.F.R. § 410.32(b)(3)(ii), or 42 C.F.R. § 410.27(f)).

Back to Top

Proposed Decision Memo

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SUBJECT: Proposed Coverage Decision Memorandum for Cardiac Rehabilitation

DATE: December 22, 2005

I. Proposed Decision

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II. Background

On February 20, 2001, CMS internally generated a formal national coverage request for supervised cardiac rehabilitation to determine if literature supports the clinical effectiveness of four additional indications; (1) heart valve repair or replacement; (2) coronary angioplasty; (3) heart or heart/lung transplant; and (4) congestive heart failure. CMS then requested, on November 5, 2001, that the Office of the Inspector General assist CMS in determining whether outpatient cardiac rehabilitation programs meet the existing physician supervision requirement. Upon receipt of the OIG's report, CMS intended to announce a new completion date for the NCD. The report resulted in a recommendation to CMS from the OIG to revise the policy to provide needed clarification. CMS had separately received similar recommendations from providers that the policy be more straightforward in addition to their requesting that the policy be revised to reduce the burden required to be compliant with the current policy.

In January 2005, CMS held a meeting of the Medicare Coverage Advisory Committee entitled *Physician-supervised behavioral interventions for patients with symptomatic coronary artery disease.* Information regarding this meeting is provided under the *MCAC* subheading in section VII(B)(4) of this document.

On June 29, 2005, CMS closed the existing reconsideration and reopened a new national coverage determination process in order to review clinical indications and additional policy concerns using current evidence.

The current NCD does not provide a definition of cardiac rehabilitation aside from describing the service as an exercise program for cardiac patients. To provide clarification, CMS has sought to adopt a well-accepted definition of cardiac rehabilitation. Cardiac rehabilitation is described by the U.S. Public Health Service as consisting of "comprehensive, long-term programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling." These programs "are designed to limit the physiologic and psychological effects of cardiac illness, reduce the risk of sudden death or reinfarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients." Additionally, cardiac rehabilitation programs aim to reduce subsequent cardiovascular-related morbidity and mortality.[1]

CMS has been evaluating, under demonstration authority, lifestyle modification programs for the treatment of coronary artery disease including Dr. Ornish's Program for Reversing Heart Disease® and the Cardiac Wellness Program of the Mind/Body Institute in Boston, Massachusetts. We believe these programs fall under the purview of this NCD. Completion of the demonstrations will allow further evaluation of the programs.

Cardiac rehabilitation developed in the 1950s from the concept of early mobilization after acute myocardial infarction.[2] The standard of care prior to cardiac rehabilitation was bedrest and inactivity after acute myocardial infarction.[3] In the 1970s, cardiac rehabilitation developed into highly structured, physician supervised, electrocardiographically-monitored exercise programs. However, the programs consisted almost solely of exercise alone.[4] Foreman et al (2000) states that "over subsequent years, cardiac rehabilitation broadened beyond exercise into a composite of cardiac risk modification. Lipid, blood pressure, and stress reductions, smoking cessation, diet change, and weight loss were coupled to goals of exercise training."

Cardiac rehabilitation programs are often divided into phases. Phase I refers to inpatient cardiac rehabilitation services. Phase II refers to outpatient medically supervised programs that are typically initiated 1-3 weeks after hospital discharge and provide appropriate ECG monitoring. Phase III refers to maintenance programs without physician supervision and monitoring.[5] This coverage decision pertains only to phase II cardiac rehabilitation.

III. History of Medicare Coverage

History of Medicare Coverage of Cardiac Rehabilitation

Since 1982, Medicare's national coverage decision has provided for phase II cardiac rehabilitation for patients who experience stable angina, have had coronary artery bypass grafts, or have had an acute myocardial infarction within the past twelve months. There have been two modifications to the policy since 1982.

The first change, issued in December 1985, clarified the payment limitation applying to freestanding clinics and the policy regarding physical therapy and occupational therapy services. The second modification, issued in August 1989, was in response to CMS's Technology Advisory Group's (TAG) clarification of physician supervision. In 1988, the TAG defined the necessary level of supervision to be that the physician must be present on the immediate premises, but not necessarily in the room.

Current Medicare National Coverage Decision Regarding Cardiac Rehabilitation

The *National Coverage Determination Manual* (manual 100-3) addresses Medicare's national coverage decision for cardiac rehabilitation in §20.10. The current Medicare national coverage decision limits coverage to only phase II cardiac rehabilitation for patients who (1) have a documented diagnosis of acute myocardial infarction within the preceding 12 months; or (2) have had coronary bypass surgery; and/or (3) have stable angina pectoris. Under the current policy, no other diagnostic categories may be covered. Contractors do not currently have the discretion to extend coverage beyond these indications. Under current policy, phase II cardiac rehabilitation programs may be provided under physician supervision either by the outpatient department of a hospital or in a physician-directed clinic.

Benefit Category

For an item or service to be covered by the Medicare program, it must meet one of the statutorily defined benefit categories outlined in the Social Security Act. Cardiac rehabilitation falls under the benefit category set forth in section 1861(s)(2)(A) of the Social Security Act (services incident to a physician's professional service). For Part B, services must be an integral, though incidental, part of the service of a physician in the course of diagnosis or treatment of an injury or illness (42 CFR 410.26(b)(2)). Medicare Part B also pays for hospital services and supplies furnished incident to a physician service to outpatients if they are furnished by or under arrangements made by a participating hospital as an integral though incidental part of a physician's services (42 CFR 410.27(a)). In the case of cardiac rehabilitation, the ordering physician is the "incident to" physician.

IV. Timeline of Recent Activities

February 20, 2001	CMS internally generates a formal national coverage request for supervised cardiac rehabilitation to evaluate whether literature supports the clinical effectiveness of physician supervised cardiac rehabilitation for the following additional indications: (1) heart valve repair or replacement; (2) coronary angioplasty; (3) heart or heart/lung transplant; and (4) congestive heart failure.
November 5, 2001	CMS requests that the Office of the Inspector General assist CMS in determining whether outpatient cardiac rehabilitation programs meet the current physician supervision requirements as outlined in the existing coverage policy. A new due date will be announced after CMS has received the OIG's report.
January 25, 2005	Medicare Coverage Advisory Committee meeting is held to discuss the evidence for Supervised Behavioral Interventions for Patients with Symptomatic Coronary Artery Disease.
June 15, 2005	CMS requests that the Agency for Healthcare Research and Quality (AHRQ) expand a previous technology assessment (available at http://www.cms.hhs.gov/mcac/id144a.pdf) to examine the components of cardiac rehabilitation programs.
June 29, 2005	Due to the length of time this reconsideration was pending, CMS closes the analysis without changing coverage for cardiac rehabilitation programs and opens a new reconsideration to review clinical indications and additional policy concerns using current evidence. At this time CMS requests public comment.

August 18, 2005	OIG issues final report.
December 12, 2005	AHRQ issues final report.

V. FDA Status

Cardiac rehabilitation is comprised of services that do not require FDA approval.

VI. General Methodological Principles

When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding of whether an item or service is reasonable and necessary for the diagnosis and treatment of illness or injury. The evidence may consist of external technology assessments, internal review of published and unpublished studies, recommendations from the Medicare Coverage Advisory Committee, evidence-based guidelines, professional society position statements, expert opinion, and public comments.

The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: (1) specific clinical questions relevant to the coverage request can be answered conclusively; and (2) the extent to which we are confident that the intervention will improve net health outcomes for patients. A fully detailed account of "General Methodological Principles of Study Design" that CMS staff utilizes to assess the relevant literature on the therapeutic or diagnostic item or service for specific conditions is available in Appendix A.

VII. Evidence

A. Introduction

This summary represents the body of evidence for cardiac rehabilitation following AMI, CABG, stable angina pectoris, heart valve repair/replacement, PTCA, heart or heart lung transplant, and congestive heart failure (CHF). Health outcomes of interest to CMS for these indications include changes in mortality, re-infarction or restenosis rates, modifiable risk factors, quality-of-life measures, and intermediate physiological outcomes. This National Coverage Analysis (NCA) focuses on the following question: "In persons age 65 years and older, what is the clinical evidence for a net health benefit from cardiac rehabilitation for the seven indications?"

B. Discussion of evidence reviewed

1. Literature Search

CMS searched the Cochrane Library, National Health Service Centre and International Network of Agencies for Health Technology Assessments databases for systematic reviews and technology assessments of cardiac rehabilitation. CMS similarly searched PubMed (1995 to present) for randomized clinical trials (RCTs) and observational studies evaluating cardiac rehabilitation for persons 65 years of age and older. General keywords included cardiac rehabilitation, core components, and secondary prevention. Studies must have presented original data, included $\leq$ 10 patients, examined primary health outcomes or intermediate physiological outcomes, and been published in peer-reviewed English language journals. Abstracts were excluded.

2. External technology assessments

OHTA Report on Cardiac Rehabilitation Programs (1991)

The Agency for Healthcare Policy and Research (AHCPR) Office of Health Technology Assessment (OHTA) performed a technology assessment assessing the benefits of cardiac rehabilitation programs for patients following heart transplantation, PCTA or heart valve surgery. The report concluded that cardiac rehabilitation programs were safe and effective in improving functional activities of patients with cardiac disease, and that transplant, PTCA, or heart valve surgery patients had no unique characteristics differentiating them from AMI, CABG, or stable angina patients regarding necessity for cardiac rehabilitation.

NHS Centre for Reviews and Dissemination (1998)

The NHS bulletin identified over 200 reviews of cardiac rehabilitation. Evaluation was acknowledged to have been difficult "due to the variability of interventions and patient populations studied." The bulletin stated "exercise improves physical aspects of recovery at no additional risk, but as a sole intervention it is not sufficient to reduce risk factors, morbidity or mortality." Also noted was that "a combination of exercise, psychological, and educational interventions is the most effective form of cardiac rehabilitation."[6]

Cochrane Collaboration Review of Exercise-Based Rehabilitation (2001)

The Cochrane meta-analysis of exercise-based rehabilitation for coronary artery disease (CAD) was based on 8440 patients in hospital and community settings following AMI (majority of participants), CABG or PTCA, or angina or CAD defined by angiography. Primary conclusions included that: (1) exercise-only intervention reduced total cardiac mortality by 31%; (2) comprehensive cardiac rehabilitation reduced total cardiac mortality by 26%; (3) neither intervention had any effect on the occurrence of non-fatal myocardial infarction; and (4) total cholesterol of patients participating in comprehensive programs was reduced significantly.[7]

Taylor, et al.'s (2004) Review and Meta-Analysis of Exercise-Based Rehabilitation

Taylor and colleagues included 48 trials and a total of 8940 patients in their systematic review and meta-analysis of RCTs of exercise-based cardiac rehabilitation for patients with coronary heart disease (CHD). Most of the trials evaluated (67%) recruited patients with AMI alone. Compared to usual care, patients who participated in rehabilitation exhibited reduced all-cause mortality (odds ratio [OR] = 0.80; 95% confidence interval [CI]: 0.68 to 0.93) and reduced cardiac mortality (OR = 0.74; 95% CI: 0.61 to 0.96); greater reductions in total cholesterol level, triglyceride level, and systolic blood pressure; as well as lower rates of self-reported smoking. There were no significant differences in rates of nonfatal myocardial infarction, CABG, and percutaneous coronary intervention (PCI), or in changes in high- and low-density lipoprotein cholesterol levels and diastolic pressure. The authors reported that cardiac rehabilitation's effect on all-cause mortality was independent of CHD diagnosis, type of cardiac rehabilitation, dose of exercise intervention, length of follow-up, trial quality, and trial publication date.[8]

AHRQ Technology Assessment of Secondary Prevention Programs in CAD (2005)

A meta-analysis of coronary heart disease management programs was provided by Clark and colleagues at the University of Alberta Evidence-based Practice Center for the AHRQ Technology Assessment Program. This review of 46 RCTs of secondary prevention in 18821 patients with CAD concluded that secondary prevention programs (for patients who are already diagnosed with cardiac disease) improved processes of care, enhanced quality of life/functional status, reduced hospitalizations, reduced recurrent myocardial infarctions, and reduced long-term mortality in patients with established CAD. The summary risk ratio (RR) equaled 0.87 (95% CI 0.79-0.97) for all-cause mortality in the 29 trials (13857 patients) reporting that outcome.[9]

The document describes this systematic review, "…demonstrates that a wide variety of secondary prevention programs delivered by health care providers, in addition to having beneficial effects on patient risk factor profiles and quality of life/functional status, provide tangible reductions in clinically relevant endpoints such as hospitalization and death."

Studies reviewed in the report and considered to provide comprehensive cardiac rehabilitation included a range of services in addition to exercise. Many included patient education, social and psychological support, nutritional counseling, stress management, and smoking cessation. Although many studies provided services beyond exercise, studies by Ornish, et al. (1990, 1998) describe a program of lifestyle modification and provided some of the most comprehensive and most intense programs to include most of the above listed components.

In addition to varying components, the studies varied greatly in program duration. Programs ranged from less than one month to over twelve months of services. The study by Ornish, et al. provides perhaps the most comprehensive follow up with some patients continuing cardiac rehabilitation for 60 months.

3. Internal technology assessments

Acute Myocardial Infarction

CMS independently searched PubMed for cardiac rehabilitation and AMI. Two additional relevant studies were identified.

Witt, *et al.* (2004) reported on a cohort of 1821 AMI survivors discharged from hospitals in Olmsted County, Minnesota between 1982 and 1998. The subjects were 58% male, and 46% of patients were $\leq$ 70 years of age. Results showed that study participants were more likely to be male, younger, and with fewer co-morbidities ($p < 0.01$ for all comparisons). Participants also had lower risk of death ($p < 0.001$) and recurrent AMI ($p < 0.049$) at 3 years, and the survival benefit associated with cardiac rehabilitation participation was stronger in more recent years (RR for 1998 versus 1982 = 0.28, 95% CI 0.18-0.43, as well as RR for 1990 versus 1982 = 0.41, 95% CI 0.33-0.52).[10]

Blumenthal, *et al.* (2005) reported an RCT of 134 patients with stable ischemic heart disease (92 men and 42 women, mean age = 63 ± 10 years) that evaluated the impact of two behavioral intervention programs on psychosocial functioning and cardiovascular risk markers. Results showed that patients in both exercise and stress management groups showed significantly greater reductions ($p = 0.02$) in general distress and depressive symptoms than usual medical care alone, but there were no between-group treatment differences in either hostility or anxiety measures. Bloomberg and colleagues concluded that 16 weeks of exercise and stress management training reduced emotional distress and improved markers of cardiovascular risk more than usual medical care alone.[11]

Coronary Artery Bypass Graft

CMS independently searched PubMed for cardiac rehabilitation and CABG. One additional relevant study was identified.

Hedback, *et al.* (2001) reported a 10 year post-op observational study of 49 consecutive Swedish patients (39 men and 10 women, mean age = 57 ± 7.4 years) who underwent elective CABG and were offered a rehabilitation program consisting of education in risk-factor control, a physical training program, and regular post-CABG clinic follow-up. The control group (78 men and 20 women, mean age = 57.3 ± 7.3 years) consisted of two well-matched CABG patients for each study patient, who were offered usual care but no access to a cardiac rehabilitation program. Results showed that, after 10 years, patients in the study group experienced longer mean time to a first adverse cardiac event compared to controls (82 months versus 66 months, $p < 0.05$), and the percent of patients who developed a cardiac event (cardiovascular death, nonfatal MI, CABG or PTCA) was significantly less in the study group compared to controls (18.4% versus 34.7%, $p < 0.05$). Additionally, the number of hospital readmissions (2.1 versus 3.5 per patient) and length of admissions (11 versus 26 days per patient) was significantly lower in the study group ($p < 0.01$). Hedback and colleagues concluded that comprehensive cardiac rehabilitation post-CABG improved long-term prognosis and reduced the need for hospital care.[12]

Stable Angina Pectoris

CMS independently searched PubMed for cardiac rehabilitation and angina. One additional technology assessment was identified.

In 2005, the AHRQ published a technology assessment (prepared by the University of Alberta Evidence-based Practice Center) on patients with established coronary artery disease. The objectives of the assessment were "to determine whether secondary prevention programs for patients with established coronary artery disease (CAD) improve health outcomes and to characterize secondary prevention programs which have been evaluated in the literature and to identify any program-related factors which influence effectiveness for patients with established coronary artery disease (CAD)."[13] A total of 46 randomized trials with 18,821 patients were reviewed. The assessment concluded: "Secondary prevention programs improve processes of care, enhance quality of life/functional status, reduce hospitalizations, reduce recurrent myocardial infarctions, and reduce long-term mortality in patients with established CAD. Although these clinical benefits are likely to reduce health care costs, there is inadequate data to conclusively comment on the cost-effectiveness of these programs and specific components contained therein. Though most programs are likely to involve specialist health professionals, physicians adopt an active coordinating role in only a small minority of programs. Programs with more individualization are more effective at reducing hospitalizations."[14]

Heart Valve Repair or Replacement

CMS independently searched PubMed for cardiac rehabilitation and heart valve surgery. One additional relevant review was identified.

Stewart, et al. (2003) reviewed the evidence for comprehensive exercise-based cardiac rehabilitation and reported that "the exercise component of cardiac rehabilitation is useful for reversing the symptoms associated with deconditioning. Women with mitral valve prostheses improved their peak metabolic equivalent capacity by 19% and their physical working capacity by 25% after undergoing an 8-week program, whereas control subjects did not improve. After aortic valve replacement, exercise training increased peak aerobic capacity and decreased rate pressure product and the rating of perceived exertion at a fixed workload. The increase in aerobic capacity in the exercise group was 38% higher than that in the control group at 6 months and was 37% higher after 12 months [Sire 1987]. In a randomized controlled study, patients who had aortic/mitral valve surgery were assigned to supervised exercise or a control group. Nevertheless, more than half of the control subjects routinely exercised on their own or joined community exercise programs. After the 3-month intervention period, peak VO_2 was improved by 25% with no group differences [Jairath, *et al.* 1995]."

The review further noted that "for most patients, enhanced functional capacity leads to a greater ability to perform the activities of daily living and to tolerate activity for a longer duration with less perceived exertion. Older patients who undergo heart valve surgery have longer hospital stays and more complications, and they require more follow-up care after hospital discharge. Cardiac rehabilitation is also an opportunity to evaluate medical management and to educate patients about the safety of increasing physical activity and monitoring symptom."[15]

Percutaneous Transluminal Coronary Angioplasty

CMS independently searched PubMed for cardiac rehabilitation, PTCA, PCI and revascularization. One review and two additional relevant studies were identified.

Stewart, *et al.* (2003) reviewed the evidence for comprehensive exercise-based cardiac rehabilitation programs following percutaneous revascularization and reported that "percutaneous interventions are effective for interrupting the process of acute coronary stenosis. Although it is fortunate that myocardial tissue damage can be avoided or minimized if the patient is treated in a timely manner, the need to treat the underlying disease that precipitated the stenosis is not changed after a revascularization procedure." The review further noted that "despite the expanded use of percutaneous revascularization, there are few controlled studies of cardiac rehabilitation after these procedures. In one study, 93 patients who had been treated with percutaneous transluminal coronary angioplasty were randomly assigned to receive a behaviorally oriented intervention or to a control group [Lisspers, et al. 1999]. After 12 months, the intervention patients, compared with the control subjects, improved significantly on self-rated measures of smoking, exercise, and diet habits. Patients also lost weight, improved their exercise capacity, and experienced less chest pain during exertion. Although the mechanisms for decreased mortality with exercise have not been fully explained, exercise training improves the lipid profile, reduces blood pressure, lowers the fasting glucose level, and reduces body fat and increases lean body mass…." Therefore, "risk factor management is no less critical for these [PTCA] patients than for those with other manifestations of atherosclerosis, even in the absence of myocardial damage, and may lead to a slowing of coronary disease progression."[16]

Belardinelli, *et al.* (2001) reported an RCT of 118 consecutive patients with CAD (mean age = 57 ± 10 years) who underwent PTCA or stenting on one (69%) or two (31%) coronary arteries. Patients were randomized into either a training group (49 men and 10 women, mean age = 53 ± 11 years) who exercised 3 times a week for 6 months at 60% of peak VO_2, or a control group (50 men and 9 women, mean age = 59 ± 10 years) who were recommended to perform daily mild physical activities but to avoid physical training. Results showed that only trained patients had significant improvements in peak VO_2 (26% increase, $p < 0.001$) and quality-of-life (26.8% increase, $p = 0.001$) versus controls. The angiographic restenosis rate was unaffected by exercise training and was not significantly different after either PTCA or stenting. During the follow-up (33 ± 7 months), trained patients had a significantly lower event rate (e.g., new AMI, angioplasty or CABG) than controls (11.9 vs. 32.2%, RR 0.71, 95% CI: 0.60-0.91, $p = 0.008$) and a lower rate of hospital readmission (18.6 vs. 46%, RR 0.69, 95% CI: 0.55-0.93, $p < 0.001$).[17]

Dendale, *et al.* (2005) retrospectively reported a cohort of 223 Dutch post-PCI patients "none of whom had experienced a cardiac event in the 3 years before PCI was performed." The training group (107 men and 33 women, mean age = 62 ± 7 years) consisted of those patients who participated in the entire 3 month multidisciplinary cardiac rehabilitation program offered by one hospital's cardiologists, and the control group (54 men and 29 women, mean age = 68 ± 8 years) were patients referred to the hospital's cath lab from an outside institution where no structured rehabilitation was offered. Results showed that the incidence of total major adverse cardiac events in the rehabilitation group was lower (24% versus 42%, $p = 0.005$) than in the controls. There was no significant between-group difference in myocardial infarction (3% versus 2%), but the incidences of documented restenosis (14% versus 23%, $p < 0.005$), recurrent angina (7% versus 20%, $p < 0.005$), need for revascularization (17% versus 30%, $p < 0.005$) and death (1% versus 6%, $p < 0.05$) were all significantly lower in the rehabilitation group compared to controls. The only risk factor significantly different between groups was hypercholesterolemia, which was present in 61% of rehabilitation patients and 85% of controls ($p < 0.005$).[18]

Heart or Heart Lung Transplant

CMS independently searched PubMed for cardiac rehabilitation and heart and heart lung transplant. Two studies and two additional reviews were identified.

In 2005, Kavanagh published a review of exercise rehabilitation for cardiac transplant patients.[19] The author noted: "The routine use of a comprehensive exercise rehabilitation program following heart transplantation improves exercise capacity, permits bouts of submaximal effort for longer periods and with less fatigue, improves muscle mass and function, and ameliorates steroid-induced osteoporosis. While maximizing the benefits of surgery, it is unlikely that it can completely restore physiological function. The prescription of exercise must take into account the denervated heart's peculiar response to effort and must place heavy reliance on perceived exertion and metabolic measurements rather than on target heart rates for defining the intensity of training."[20]

In 2003, Stewart and colleagues discussed the scientific and clinical evidence for cardiac rehabilitation in patients who underwent heart transplant.[21] The authors noted: "Although the studies reviewed are small, there is sufficient evidence that cardiac rehabilitation improves physiologic hemodynamic responses and helps to preserve or reverse bone and muscle loss (Table 1). Dealing with the continued medical consequences of cardiac transplantation is challenging, and the multidisciplinary nature of cardiac rehabilitation, including exercise, education, nutrition, and behavioral interventions, is ideally suited to these patients. One study reported that heart transplantation in selected patients who were $\leq$ 70 years of age could be performed with similar morbidity, mortality, and intermediate-term survival as found in younger persons. Although the efficacy of cardiac rehabilitation for elderly heart transplant patients has not been studied, it would be expected that the same benefits as demonstrated in younger persons would result in these patients."[22]

In 2003, Kavanagh and colleagues published the results of a case control study on exercise capacity following heart transplant. Thirty six cases were enrolled and received 16 months of outpatient exercise training which involved walking, progressing to jogging if tolerated, initially a distance of 1.6 km 5 times weekly. All patients completed the program. The final assessment was performed an average of 12 years after the program. Of the 36 men, 20 were evaluated. Mean age was 48 years. Thirteen patients had died and 3 were lost to follow up. At 16 months, there was a significant increase of 26% on average in peak oxygen intake, as measured by progressive cycle ergometry test. Over the follow-up period, "gains in exercise capacity are lost over 12 years at a rate commensurate with normal aging."[23] In this study, univariate and multivariate analyses were used. Controls were age matched men who were not regularly exercising and used to establish changes with aging.

In 2001, Hummel and colleagues published the results of a case series study on quality of life after heart and heart-lung transplant. Of the 369 cases, 350 had heart transplantations and 19 had heart-lung transplants. Patients were entered into a phase-II rehabilitation program. Mean age of heart transplant patients was 48 years. Mean age of heart-lung transplant patients was 31 years. Physical condition was evaluated by maximum possible workload during 15 minute bicycle exercise. Quality of life was assessed with the SF-36 questionnaire. All patients completed the program. Of the 369, 250 (62%) were able to exercise 25-50 watts. Most patients (90% of a subgroup of 61 patients tested) reported good or very good physical condition. The authors concluded that: "Shortly after transplantation most of the transplanted patients estimated their personal status positively, even though their physical capabilities were largely impaired at that time."[24] In this study, the composition of the rehabilitation program was not reported. Statistical methods were not fully described.

Congestive Heart Failure

CMS independently searched PubMed for cardiac rehabilitation and heart failure. Four additional studies and 5 reviews were identified.

In 2005 (in press), Jonsdottir and colleagues reported the results of a randomized trial on supervised training in patients with chronic heart failure. Chronic heart failure was defined as New York Heart Association class II or III[25] and having an hospitalization due to CHF. Primary outcomes included 6-minute walk distance, muscle strength, and quality of life. Forty three patients were randomly assigned to exercise (n=21) or a control group (n=22). The program included supervised aerobic and resistance training twice a week for 5 weeks. Mean age was 68 years. About 80% were men. At the end of the program, the authors found significant improvements in 6-minute walk distance, muscle strength, and quality of life.[26] In this study, left ventricular ejection fraction was not reported as an inclusion criterion.

In 2005, Witham and colleagues reported the results of a trial on exercise in older patients with heart failure. Heart failure was defined according to the European Society of Cardiology guidelines, New York Heart Association class II or III, and evidence of left ventricular systolic dysfunction. The primary outcome was 6-minute walk distance. Eighty-two patients were randomly assigned to exercise (n=41) or usual care. The exercise program lasted about 20 minutes and was offered twice a week for 3 months. After the initial 3 months, patients in the exercise group were asked to continue exercises at home 2-3 times per week. Mean age was about 80 years. There were more men (63%) in the exercise group than the control group (46%). At the 6 month follow-up, there were no significant differences between groups on 6-minute walk distance and quality of life.[27] In this study, the level of left ventricular systolic dysfunction used as an inclusion criterion was not reported. The program included aerobic and strengthening exercises. A physiotherapist delivered the exercise intervention.

In 2004, Austin and colleagues reported the results of a trial to "to determine whether a cardiac rehabilitation programme improved on the outcomes of an outpatient heart failure clinic (standard care) for patients, over 60 years of age, with chronic heart failure."[28] Heart failure was defined as New York Heart Association class II or III, left ventricular systolic dysfunction (ejection fraction $\geq$ 40%), confirmed by echocardiography. The primary endpoints were functional status (NYHA class I–IV), functional performance (6-minute walk test), perceived exertion (Borg Rating of Perceived Exertion), and health-related quality of life in terms of disease specific (Minnesota Living with Heart Failure survey) and cost utility (EuroQol - European Qualify of Life index) questionnaires. Two hundred patients were randomly assigned to cardiac rehabilitation (N=100) or standard care (n=100). The program consisted of an 8 week rehabilitation program, educational sessions, and counseling. Patients had sessions two times per week for 2.5 hours. After the initial 8 weeks, patients had weekly 1 hour sessions for 16 weeks. At the 24 week follow-up, the authors noted "significant improvements in MLHF and EuroQol scores, NYHA classification and 6-minute walking distance (meters) at 24 weeks between the groups ($p<0.001$)."[29] In this study, the exercise was not specifically reported. A clinical nurse specialist coordinated the exercise.

In 2004, van den Berg-Emons and colleagues reported the results of a clinical trial "to assess whether aerobic training leads to a more active lifestyle and improved quality of life (QoL) in patients with CHF."[30] Patients with stable heart failure, NYHA class II or III, and ejection fraction < 40% were included. Thirty-four patients were randomly assigned to training (n=18) or control (n=16) groups. Training consisted of cycling, walking and aerobic games and was performed 2 times per week for 1 hour. Mean age was 59 years. Men comprised 74% of the study population. After 3 months, there were no significant changes in lifestyle and quality of life. The authors concluded that "at group level training did not result in a more active lifestyle or improved QoL."[31]

The Heart Failure – A Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION) is a large ongoing trial funded by NIH to examine the effects of exercise training on mortality and morbidity of patients with heart failure.[32] It aims to enroll 3000 patients at 70 U.S., Canadian, and European sites. The primary hypothesis is that "exercise training in patients with LV systolic dysfunction will reduce the combined primary end point of all cause deaths and hospitalizations by 20% over 2 years vs. a usual-care group."[33] Inclusion criteria included heart failure due to left ventricular systolic dysfunction, ejection fraction $\geq$ 35%, NYHA class II-IV, and stable optimal medical therapy. The exercise program consists of treadmill or bicycle exercise three times a week for the first 3 months at the participating site.[34]

In 2005, Ko and McKelvie reported the findings of a systematic review of exercise training in patients with heart failure. The authors noted: "Heart failure (HF) is characterized by dyspnea and fatigue leading to exercise intolerance. HF patients have been advised to avoid exercise because of concerns about detrimental cardiac effects. However, in many studies on the effects of exercise training, HF patients have demonstrated beneficial outcomes. Furthermore, exercise training has been found to be safe. Recent studies have demonstrated that exercise training might reduce morbidity and mortality. Although these data are promising, confirmation is required from a large clinical trial powered to examine the effect of exercise training on morbidity and mortality."[35]

In 2005, Delagardelle and Feiereisen reported the findings of a systematic review of strength training for patients with chronic heart failure. The authors noted: "Due to the specific loss of muscular mass, function and strength in advanced CHF, application of strength training should be considered as a logical answer to address muscle wasting. Strength training has to be applied by well trained therapists in an adapted infrastructure and regular supervision of the patients has to be provided. Actual recommendations state that strength training should only be applied in hospital or rehabilitation centres and that careful, individually adapted programs are needed. Adequate training of therapists is required to promote strength training on a larger scale.

Strength training can add to the quality of life of CHF patients as their daily life activities are often limited by the loss of muscular strength. It further improves balance, reducing falls and increases bone density in those (often old-aged) patients. For the moment, large trials are lacking, especially because training is not as largely funded as other therapeutic interventions in CHF like new drugs or resynchronization therapy. Thus it is difficult to compare the effects of training therapy to other proven therapeutic options. As CHF is a disease which is also very frequent in countries where expensive therapeutic options cannot be afforded, training therapy should be recommended and promoted by the world wide cardiology community."[36]

In 2004, Rees and colleagues presented the findings of a Cochrane review on exercise based rehabilitation for heart failure. They reported: "Exercise training improves exercise capacity and quality of life in patients with mild to moderate heart failure in the short term. One study found beneficial effects of exercise on cardiac mortality and hospital readmissions over 3 years of follow-up, the remaining included studies did not aim to measure clinical outcomes and were of short duration. The findings of the review are based on small-scale trials in patients who are unrepresentative of the total population of patients with heart failure. Other groups (more severe patients, the elderly, women) may also benefit. Large-scale pragmatic trials of exercise training of longer duration, recruiting a wider spectrum of patients are needed to address these issues."[37]

In 2004, the ExTraMATCH collaborative group reported the results of a meta-analysis to determine the effect of exercise training on survival in patients with heart failure. Randomized controlled trials of exercise training for at least eight weeks with individual patient data on survival for at least three months were included. Nine studies through 2002 with 801 patients (395 exercise training, 406 controls) were reviewed. The primary outcome was death from all causes. The authors found that "during a mean (SD) follow up of 705 (729) days there were 88 (22%) deaths in the exercise arm and 105 (26%) in the control arm" (hazard ratio 0.65, 95% confidence interval, 0.46 to 0.92).[38] They concluded: "Meta-analysis of randomised trials to date gives no evidence that properly supervised medical training programmes for patients with heart failure might be dangerous, and indeed there is clear evidence of an overall reduction in mortality. Further research should focus on optimising exercise programmes and identifying appropriate patient groups to target."[39]

In 2003, Stewart and colleagues discussed the scientific and clinical evidence for cardiac rehabilitation in patients with CHF.[40] They noted: "Patients with heart failure often experience fatigue and dyspnea with exertion. Although the primary pathology of heart failure results from abnormalities in cardiovascular function, abnormalities in peripheral blood flow, skeletal muscle morphology, metabolism, strength, and endurance all contribute to the heart failure syndrome. Several trials have shown that cardiac rehabilitation improves disease-related symptoms, quality of life, and clinical outcomes. Overall, prescribed exercise attenuates the fatigue and dyspnea that limit exercise intolerance. The improvements ranged from 15 to 30% in peak VO2, which is greater than or equal to the gains in exercise capacity observed in many clinical drug trials."[41]

4. MCAC

A meeting of the Medicare Coverage Advisory Committee entitled *Physician-supervised behavioral interventions for patients with symptomatic coronary artery disease (CAD)* was held in January 2005. Meeting materials and detailed information are available at http://www.cms.hhs.gov/mcd/viewmcac.asp?where=index&mid=27. The MCAC only reviewed evidence for symptomatic coronary artery disease and did not evaluate all of the requested indications in this NCA.

In summary, a technology assessment provided evidence that secondary prevention programs improve processes of care, enhance quality of life/functional status, reduce hospitalizations, and reduce long-term mortality in patients with established CAD. The weight of the published randomized trial evidence suggests that comprehensive secondary prevention programs positively impact on processes of care (risk factor profiles, use of proven efficacious therapies) which are closely linked to subsequent morbidity and mortality in patients with CAD. Pooling the data from those trials which reported subsequent rates of MI does reveal a trend towards reduction in recurrent MIs over a median follow-up of 12 months; the majority of these programs also demonstrate improved symptom scores, exercise tolerance, or quality of life in participants. The mortality benefit derived from participation in the secondary prevention programs was apparent with longer lengths of follow-up. There was a statistically significant 15% reduction in hospitalizations.

The panel voted to inform CMS that for the purpose of the panel's recommendations, physician-supervised behavioral interventions refer to interventions that are comprehensive, intensive and multidisciplinary. On the question of how well the evidence addresses the effectiveness of physician-supervised behavioral interventions for patients with symptomatic CAD as compared to usual medical/surgical management, the panel voted that the evidence was reasonably well. On the question of how well the evidence addresses the effectiveness of physician-supervised behavioral interventions for patients with symptomatic CAD the panel voted that they were moderately to highly confident in cases of cardiac event including angina, long-term survival, short-term survival and quality of life. Concerning the likelihood that the therapy would produce a clinically important net health benefit in the treatment of patients with symptomatic CAD, the panel voted that they were moderately to highly confident that it would and that, based on the evidence, they were moderately confident that the results could be generalized to the Medicare population (aged 65+).

5. Evidence-based guidelines

AHCPR Cardiac Rehabilitation Clinical Practice Guideline (1995)

The AHCPR guideline's specific recommendation was that "elderly coronary patients have exercise trainability comparable to that of younger patients participating in similar exercise rehabilitation. Elderly female and male patients show comparable improvement. Referral to and participation in exercise rehabilitation is less frequent at elderly age, especially for elderly females. No complications or adverse outcomes of exercise training at elderly age were described in any study. Elderly patients of both genders should be strongly encouraged to participate in exercise-based cardiac rehabilitation."[42]

6. Professional Society Position Statements

Balady, et al. (2000) Core Components of Cardiac Rehabilitation/Secondary Prevention Program

In 2000, the AHA and AACVPR issued a joint scientific statement outlining the core components, expected outcomes, and interventions of cardiac rehabilitation programs.[43] The purpose of this statement was to provide a foundation for and assistance to staff in design and development of cardiac rehabilitation programs, with emphasis on a comprehensive multifaceted approach. The stated core components of cardiac rehabilitation/secondary prevention programs included:

- Baseline patient assessment
- Nutritional counseling
- Risk factor management (lipids, hypertension, weight, diabetes, and smoking)
- Psychosocial management
- Physical activity counseling
- Exercise training

AHA Statement: Secondary Prevention of Coronary Heart Disease in the Elderly (2002)

With particular emphasis on patients ≤ 75 years of age, this AHA statement concluded that "secondary prevention interventions to impact and control risk factors in older patients with CHD, including habitual cigarette smoking, hypertension, abnormal blood lipids, elevated blood glucose, obesity, various psychological concerns, and physical inactivity, appear effective to an extent similar to that observed in younger patients. Greater involvement of the elderly in these programs is needed to fully realize the therapeutic and secondary preventive potential."

In its section on management of prescribed exercise for increasing activity and fitness, the AHA statement noted that "modification of the components of the exercise prescription should be considered for elderly patients, particularly those ≥ 75 years of age and those with significant comorbidities that limit mobility, e.g., arthritis, pulmonary disease, and peripheral arterial disease. Increasing caloric expenditure and enhancement of functional mobility should be emphasized, as well as participation in activities that increase socialization with others. The latter is paramount to combating feelings of isolation and depression. Increasing frequency and duration of exercise sessions should supersede increases in intensity and progression to reduce the potential for overuse injuries. Strength training for elderly patients as a component of the overall exercise prescription should improve neuromuscular function, muscular strength, and endurance. Such training is essential to improving responses to the various physical demands of daily living as well as occupational and recreational activities. Furthermore, it is likely to improve functional independence and self-esteem, while reducing the risk of injury associated with musculoskeletal overuse and falls."[44]

AHA Statement: Cardiac Rehabilitation and Secondary Prevention of CHD (2005)

In 2005, the AHA updated its 1994 scientific statement on cardiac rehabilitation, reviewed the core components for effective rehabilitation/secondary prevention programs, and provided detailed research recommendations. In 1994, for example, the AHA carefully noted that the body of literature was clearly lacking with respect to studies on specific populations, e.g, women, elderly, and minorities. In 2005, the AHA noted that evaluations were still needed "to determine the effectiveness and safety of a variety of approaches designed to increase patient referrals, accessibility, and delivery of cardiac rehabilitation and secondary prevention services and to promote adhere to program components…" In its 2005 statement, the AHA also reinforced and recommended that "randomized trials are needed to better define the role of exercise therapy for safely improving functional capacity, reducing cardiovascular symptoms, and enhancing the quality of life among specific subgroups of CVD patients, particularly older, female, and ethnic minority patients…"[45]

Professional Society Public Comments

During the initial 30-day comment period, CMS received comments from seven professional societies, the AHA, the American College of Cardiology (ACC), the AACVPR, the American College of Sports Medicine (ACSM), the American Physical Therapy Association (APTA), the Iowa Hospital Association, and the Illinois Hospital Association. The full text of these comments can be found at http://www.cms.hhs.gov/mcd/viewpubliccomments.asp?nca_id=164.

Clinical Evidence - General
The American Physical Therapy Association provides general clinical evidence to support cardiac rehabilitation. They cite several reviews, studies and clinical trials which showed improvements in exercise capacity, cardiac risk factors, hospital admissions rates and quality of life in elderly patients after participating in cardiac rehabilitation programs, thus demonstrating the benefit of cardiac rehabilitation, especially when combined with education and lifestyle modification.

Clinical Evidence for Acute MI
The AHA, AACVPR, ACC, and ACSM cite meta-analyses, studies, reviews, and trials which demonstrate the benefit of cardiac rehabilitation in patients who experience acute AMIs. Specifically these patients experience significant decreases in mortality, decreases in recurrent AMIs, an overall survival benefit in women and patients over age 70, improvements in physical function and performance of activities of daily living with programs including resistance training, and decreases in physical disability.

Clinical Evidence for Post CABG
The AHA, AACVPR, ACC, and ACSM cite numerous studies which have demonstrated the ability of cardiac rehabilitation programs to improve functional capacity in patients ages 65 and older, especially in patients who undergo CABG surgery who are considered severely disabled. They acknowledge, however, that evidence of a benefit due to cardiac rehabilitation was less clear in older subsets of patients after CABG surgery. They refer to a controlled trial involving cardiac rehabilitation after CAGB surgery with a 10 year follow up which documented a reduction in hospital readmissions and cardiovascular events. A second study showed that improvements in exercise capacity were correlated with a decrease in long term mortality rates of patients after CABG surgery and AMI, following participation in a cardiac rehabilitation program.

Clinical Evidence for Stable Angina
The AHA, AACVPR, ACC, and ACSM cite an article and study to demonstrate the benefit of exercise training in improving exercise tolerance in patients experiencing chronic stable angina pectoris and in increasing functional capacity and reducing coronary events as compared to patients who underwent invasive PCI.

Clinical Evidence for Post Heart Valve Replacement
The AHA, AACVPR, ACC, and ACSM cite a 2003 article which establishes that available data for patients who have undergone heart valve surgery supports improvements in physiological functioning and quality of life due to participation in cardiac rehabilitation programs. They also cite a 1991 statement by the AHCPR confirming that cardiac rehabilitation programs are beneficial in patients who have undergone cardiac valve surgery. These organizations cite studies that reveal that before cardiac valve surgery, most patients have very low exercise capacities with cardiovascular characteristics similar to heart failure patients. Their comments refer to studies which further support the benefit of cardiac rehabilitation programs in valve replacement patients showing improvements in physiological functioning, exercise capacity, and quality of life as compared to control groups especially in elderly patients as well as women after mitral valve replacement.

Clinical Evidence for Post Angioplasty
The AHA, AACVPR, ACC, and ACSM refer to findings of multiple studies and trials which associated participation in cardiac rehabilitation programs after PCI with numerous physiological improvements, decreased morbidity and hospital readmission rates, and improved quality of life. They further cite studies addressing unique physiological characteristics of the elderly, like the risk of restenosis in PCI patients, and benefits of exercise and risk reduction in improving these characteristic by slowing the progression of coronary artery disease. They also cite the importance of cardiac rehabilitation programs in identifying signs and symptoms of restenosis early and also in providing education and medical interventions to reduce the risk of future events.

These societies state that because the underlying disease process is the same in PCI patients as in other coronary patients they have the same needs for improving exercise capacity and reducing risk factors, and can experience the same benefits.

Clinical Evidence for Post Heart or Heart-Lung Transplant
The AHA, AACVPR, ACC, and ACSM focus their attention on several studies that examined the exercise response of patients after heart transplant and found that exercise capacity is significantly reduced as compared to same age non-transplant patients.

They assert that a number of studies since the early 1980’s have demonstrated the potential of exercise training to reverse or diminish many physiological abnormalities observed in heart transplant patients, reported improvements in endurance capacity, increases in lean body mass, decreases in fat mass, and established the importance of resistance training to increase bone mineral density.

Also cited is the first randomized trial of heart transplant patients where patients randomized to a medically supervised cardiac rehabilitation program increased their oxygen uptake and peak workload significantly more than home exercise patients but revealed no difference between the groups in use of anti-hypertensive medications, number of rejections and infections, and weight gain.

Clinical Evidence for Congestive Heart Failure
The AHA, AACVPR, ACC, and ACSM refer to more than two dozen controlled trials which have assessed the effects of exercise training in CHF patients, most age 65 and older, with each trial demonstrating the benefit of exercise in reducing fatigue and improving exercise capacity. In various studies, improvements in shortness of breath, ability to perform activities of daily living, anxiety, depression, and well-being were observed as well as improvements in left ventricular ejection fraction and reverse remodeling.

The societies go on to cite the European Heart Failure Training Group's report that no adverse exercise training-related side effects were reported in the results from randomized controlled trials at seven separate centers, involving 134 CHF patients and note that physician involvement to monitor, evaluate, and care for complications, was required in the heart failure exercise trials to date. They also refer to a 2002 trial that reported no exercise training-related effect on clinical outcomes.

Appropriate Level of Physician Supervision
The AHA, AACVPR, ACC, and ACSM state that the current coverage requirements contradict the Medicare Intermediary Manual requirements at 3112.4 A, which states that the physician supervision requirement is assumed to be met when services are performed on hospital premises. They suggest removing the requirement that a physician be in the area of the exercise room for hospital-based programs due to a lack of clinical basis for such requirement. The Iowa Hospital Association's comments closely reflect these.

The four societies believe that when cardiac rehabilitation is provided in a physician's office or outpatient facility requiring immediate availability of a physician is reasonable. They suggest two levels of physician supervision: (1) program medical director overseeing the program but not required to be physically present; and (2) emergency supervision/consultation from the emergency department staff and a "code" team.

The APTA believes that physician supervision of physical therapy services in cardiac rehabilitation programs should not be required because Congress has defined these services without requiring physician supervision for independent practitioners in Section 1861 of the Social Security Act, and physical therapists' education, clinical training, and licensing requirements qualify them to provide cardiac rehabilitation services.

The Illinois Hospital Association agrees that a physician should not be required to be physically present in the exercise room and that services should be conducted under "general supervision" of an available physician.

"Incident to"
The AHA, AACVPR, ACC, and ACSM identify three appropriate options for meeting the "incident to" requirement. They believe that cardiac rehabilitation services can be incident to (1) a patient's primary care physician; (2) the referring physician (usually cardiologist); or (3) the rehabilitation program's medial director. The Iowa Hospital Association also contends that the "incident to" physician could be a patient's primary care physician, the referring physician, or a hospital based physician who the patient visits. To ensure that services are "incident to," documentation of interactions between the physician, CR staff, and patient must be in medical records.

The APTA believes that physical therapists have the training and education so as not to require "incident to" supervision by a physician.

Individual Components of Cardiac Rehabilitation Programs
The AHA, AACVPR, ACC, and ACSM believe that cardiac rehabilitation programs should include a multidisciplinary approach to overall cardiovascular disease risk reduction. The AACVPR and AHA delineated the components necessary for a comprehensive program and include: (1) patient assessment; (2) exercise training; (3) education and counseling involving a) physical activity counseling; b) nutritional counseling; c) lipid management; d) blood pressure management; e) smoking cessation; f) weight management; g) diabetes management; and h) psychosocial management.

The APTA indicates that components should include a medical or program director, cardiac rehabilitation nurses, physical therapists or exercise physiologists, a clinical psychologist, pharmacist, and dietitian.

Appropriate Number of Cardiac Rehabilitation Sessions
The AHA, AACVPR, ACC, and ACSM believe that CMS should not limit 36 monitored sessions to a 12 week time period but should allow individualization for each patient for up to 52 weeks and base this suggestion on several studies demonstrating benefits from extending exercise training beyond 12 weeks.

The APTA suggests that CMS change the current number of sessions to allow flexibility in treatment planning and believe this is appropriate due to the various levels of need from different cardiac conditions.

7. Expert Opinion

Other than as stated above, CMS received no comments identified as expert opinions during the initial 30-day comment period.

8. Public Comments

CMS received public comments from 30 different groups and individuals. Of these comments, 10 specifically address the overall benefits of cardiac rehabilitation programs as demonstrated through improvements in quality of life and functional capacity, detection of signs and symptoms of cardiovascular events early, and reductions in hypertension, cholesterol levels and mortality. The full text of these comments is available at http://www.cms.hhs.gov/mcd/viewpubliccomments.asp?nca_id=164.

Evidence for Health Benefit from CR for Seven Indications
All commenters agree that coverage should be continued for the three current indications and extended to the four additional indications.

One commenter contends that other insurance carriers cover cardiac rehabilitation costs for AMI, CABG, stable angina, PTCA/stents, valve replacement, and CHF. One commenter asserts that many PTCA patients would have previously undergone bypass surgery, which would have enabled them to participate in cardiac rehabilitation programs, therefore those who undergo PTCA should still be able to participate in cardiac rehabilitation.

Five commenters state that exercise programs are beneficial to valve replacement, CHF, and heart/heart-lung transplant patients who are usually weak and deconditioned. Exercise in these populations then works to improve their overall health and quality of life.

One commenter identifies the benefit of monitoring CHF and valve replacement patients in cardiac rehabilitation programs in detecting arrhythmias early and preventing further complications.

One commenter cites a study in which 31 out of 68 patients, taking part in an exercise program while awaiting heart transplants, found their exercise tolerance to improve enough for them to be removed from the transplant list.

The Appropriate Level of Physician Supervision
Most commenters express significant disagreement with a physician supervision requirement. One commenter states that a physician should provide close observation while another commenter claims that constant physician supervision should not be a requirement. One commenter believes that any physician with cardiac training should be an appropriate supervisor. Six commenters state that appropriate supervision can be met by a medical director, located in the same building, who oversees the cardiac rehabilitation program, visits the exercise room regularly, and can visit more if needed.

Two commenters believe that physicians should be involved, but more important is improving communication between the supervising physician and the cardiac rehabilitation staff. One commenter states that cardiac rehabilitation should be held to the same physician supervision requirements as other outpatient hospital services.

Four commenters contend that competent and clinically trained staff provide the appropriate supervision to carry out a physician’s program plans and that physicians can better spend their time elsewhere. Six commenters state that physicians should only be required to be nearby and emergency department physicians and code teams should be adequate to meet the supervision requirement.

Finally, 10 commenters express their concerns that a direct physician supervision requirement would place a great burden on small and rural healthcare facilities potentially causing cardiac rehabilitation programs to close and thus significantly limit patient access to cardiac rehabilitation services.

To Which Physician Should Services be "Incident To"

The commenters express various positions regarding to which physician cardiac rehabilitation services should be "incident to." One commenter states that the "incident to" physician should be a cardiologist, another commenter states that the physician should be the physician supervising cardiac rehabilitation services, and one commenter states that the "incident to" physician could be either a cardiologist or the cardiac rehabilitation "medical director." Two commenters explain that services should be "incident to" the referring physician, preferably a cardiologist or the patients' primary care physicians, while another commenter asserts that services should not be "incident to" the referring physician in order to avoid complications and increases in cost. Finally, two commenters maintain that services should be "incident to" any physician, and one commenter states that services should be "incident to" the hospital-clinic provider.

Individual Components of Program

Eight commenters agree that individualized education addressing nutrition, medication, stress and disease management, and lifestyle changes is a necessary component of cardiac rehabilitation programs. Five commenters stress the importance of individualized exercise programs which account for each patient's level of conditioning and contraindications and one commenter identified the importance of monitoring patients' physiological response to exercise.

One commenter identifies the initial assessment as an important component. One commenter cites social support from other patients as an important component. One commenter recognizes the use of established community programs as an important component.

Appropriate Number of Rehab Sessions

In addressing the appropriate number of cardiac rehabilitation sessions needed to achieve a net health benefit, five commmenters contend that an average of 36 sessions is appropriate to allow patients' to meet their goals. Five other commenters argue that the number of sessions should be individualized and depend on each patient's level of conditioning and individual goals.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

A. Analyzing Clinical Evidence

In analyzing the evidence, CMS asked: "In persons age 65 years and older, what is the clinical evidence for a net health benefit from cardiac rehabilitation for the seven indications?"

Acute Myocardial Infarction

In 1998, the NHS Centre for Reviews and Dissemination commented that "the evaluation of the cardiac rehabilitation literature is difficult, due to the variability of interventions and patient populations studied, methodological problems, and poor quality reporting. There is very little detail of randomization procedures or of the interventions provided, and study sample sizes have tended to be small. In addition, the use of care 'packages' complicates the evaluation of individual interventions as it is difficult to identify the impact of the specific components. The majority of studies include only low-risk, male, white, middle-aged MI patients and exclude, or enroll only a small number of, women, the elderly, ethnic minorities, and other cardiac patient groups such as those following cardiac surgery, heart failure or heart transplantation, thereby limiting the generalizability of the results."[46]

While both the NHS (1998) and Cochrane Collaboration (2001) reviews reported that exercise-based cardiac rehabilitation was effective in reducing cardiac mortality, it was unclear whether an exercise-only program or comprehensive cardiac rehabilitation was more beneficial. Most of the 27 further RCTs included in Cochrane's 2001 review were published since its original meta-analyses in the late 1980s, and Cochrane's 2001 review postulated that differences between programs may have been due to different medications taken during the trials. While details were not always given, none of patients in the five new trials in the exercise-only analysis appeared to have received statins, less than 50% (where stated) were on β blockers, and the Cochrane reviewers were unable to determine if thrombolysis was given on admission. Although more patients appeared to have been prescribed statins or β blockers, there were reportedly few details regarding medications or thrombolysis in the 15 new trials (8 published since 1995) included in this comprehensive cardiac rehabilitation intervention analysis.

In 2004, Taylor and colleagues' meta-analysis of RCTs of exercise-based rehabilitation for patients with CHD reported that cardiac rehabilitation's effect on all-cause mortality was independent of a patient's CHD diagnosis, type of cardiac rehabilitation, dose of exercise intervention, length of follow-up, trial quality, and trial publication date. Answering some earlier concerns, Taylor's stratified meta-analyses noted that rehabilitation's effect on total mortality was independent of whether publication was before 1995 (26 trials; OR = 0.84; 95% CI: 0.73 to 0.97) versus 1995 or later (six trials; OR = 0.62; 95% CI: 0.38 to 1.04). Considering the overlapping confidence intervals, this and other subgroup differences were not considered to be statistically significant.[47] Subsequent authors, still wondering whether older studies might not be directly applicable to modern patients harboring less ischemia due to reperfusion therapy plus better pharmacologic and revascularization techniques, have suggested that based upon Taylor's analyses the mortality benefits of cardiac rehabilitation persist in contemporary cardiology practice.[48]

In 2005, AHRQ's technology assessment added further corroboration for the benefits of cardiac rehabilitation. That systematic review and meta-analysis concluded that "secondary prevention programs improve processes of care, enhance quality of life/functional status, reduce hospitalizations, reduce recurrent myocardial infarctions, and reduce long-term mortality in patients with established CAD."[49]

While continued study is certainly encouraged, the evidence reviewed is considered adequate and overall supports the continuation of Medicare's current coverage of cardiac rehabilitation for patients following AMI.

Coronary Artery Bypass Graft

In 1995, the AHCPR Clinical Practice Guideline found improvements in the measures of exercise tolerance in five of the six nonrandomized controlled trials that involved patients after CABG surgery. As noted in the panel's conclusions for the exercise tolerance section, "the beneficial effect of cardiac rehabilitation exercise training on exercise tolerance is one of the most clearly established favorable outcomes in the panel's review." [50]

In Hedback, *et al.'s* (2001) non-randomized 10 year follow-up of 49 consecutive Swedish patients post-CABG, only the long-term follow-up of study endpoints, e.g., the results showing significant decreases in post-operative cardiac events (cardiovascular deaths, AMI, CABG or PTCA) and hospital readmissions, had a prospective design. The authors acknowledged that their lack of consistent control patient data precluded reporting any group differences in risk factor management, such as for dietary modifications, smoking cessation, and serum cholesterol levels. Similar to most other observational studies that generally evaluated the global effectiveness of exercise-based cardiac rehabilitation programs, i.e., those that only reported results on all subjects collectively, Hedback and colleagues' study was not designed to analyze any potential differential contributions of the core components of their comprehensive rehabilitation program. Thus, "no specific explanations for the reduction of cardiac events can be given."[51]

Most of the RCTs examined in Taylor, *et al.'s* (2004) review recruited patients with AMI alone, and the remaining trials recruited either exclusively CABG and PCI patients or both groups of post-revascularization patients. Taylor's meta-analysis, however, noted that reduction in all-cause mortality reported for cardiac rehabilitation patients versus control patients receiving usual medical care was independent of the CHD diagnosis. While the stratified meta-analyses showed that the reduction in total mortality following cardiac rehabilitation varied between myocardial infarction-only trials versus all other trials, Taylor and colleagues reported there were likely no statistically significant subgroup differences. There were also no statistically significant differences between those trials judged to be either exercise-only programs versus comprehensive cardiac rehabilitation.[52]

While continued study is certainly encouraged, the evidence reviewed is considered adequate and overall supports the continuation of Medicare's current coverage of cardiac rehabilitation for patients following CABG surgery.

Stable Angina Pectoris

There have been many studies on cardiac rehabilitation and exercise in patients with angina pectoris and coronary artery disease. A recent review by AHRQ found that secondary prevention programs including cardiac rehabilitation programs "improve processes of care, enhance quality of life/functional status, reduce hospitalizations, reduce recurrent myocardial infarctions, and reduce long-term mortality in patients with established CAD."[53]

While continued study is certainly encouraged, the evidence reviewed is considered adequate and overall supports the continuation of Medicare's current coverage of cardiac rehabilitation for patients with stable angina pectoris.

Heart Valve Repair or Replacement

Based on the available published literature in 1991, the OHTA stated that "it would seem that rehabilitation programs, both in and out of the hospital, are beneficial to patients who have had cardiac valve surgery and have the potential but lack the necessary functional capacities to resume normal daily activities." The OHTA report also discussed that the necessity to enroll in a cardiac rehabilitation program was dependent on each patient's degree of debilitation.[54]

Needs, therefore, for various comprehensive cardiac rehabilitation services greatly vary dependent upon each patient's symptoms, degree of debilitation, and age. Nonetheless, many of the worldwide post-op studies of aortic and mitral valve replacement enrolled predominantly male and middle-aged patients (45-65 years). Long term durability and generalizability of reported improvements in exercise tolerance and HRQL after cardiac rehabilitation post-cardiac valvular surgery thus still require careful investigation. Such studies especially should include representative numbers of Medicare patients with co-morbidities, the old (66-75 years) and very old (>75 years), plus surgical patients with more moderate to marked levels of pre-op deconditioning and impaired LV function.

While continued study is certainly encouraged, the evidence reviewed is considered adequate and overall supports the addition of Medicare coverage of cardiac rehabilitation for patients following heart valve repair or replacement.

Percutaneous Transluminal Coronary Angioplasty

Based on the available published literature identified in 1991, the OHTA reported that "most observations indicated that patients undergoing successful restoration of coronary circulation by PTCA had minimal need for formal rehabilitation programs, especially the exercise training aspects." The OHTA also stated that "early observations tended to support the belief that patients had a rapid rate of return to work and quickly resumed recreational activities after successful angioplasty." Importantly, however, the OHTA accurately noted that "early reports of excellent return-to-work rates after PTCA may have been the result of selecting 'healthier' patients for PTCA who had single-vessel coronary artery disease and well-preserved left ventricular function. In addition, the earlier patients undergoing PTCA were generally younger and had a relatively low incidence of previous myocardial infarction and shorter durations of angina. These patients were also thought to have had lower levels of physical disability before treatment and were expected to show a high rate of return to work." [55]

Accordingly, while some Medicare patients may have minimal debilitation after PTCA and may resume their normal daily activities without participation in formal rehabilitation programs, other disabled or elderly patients may retain the sick role for variable periods of time following PTCA or may be more debilitated and thus have greater need for cardiac rehabilitation services.

In Dendale and colleagues' (2005) retrospective review of 223 non-consecutive patients, only those post-PCI patients who completed one hospital's entire 3 month comprehensive rehabilitation program were included for analysis in the training group (n = 140). The incidence of total major adverse cardiac events for patients in the rehabilitation group was significantly lower (24% versus 42%, $p = 0.005$) than in control patients. The incidence of documented re-stenosis (14% versus 23%, $p < 0.005$), recurrent angina pectoris (7% versus 20%, $p < 0.005$), need for revascularization (17% versus 30%, $p < 0.005$) and death (1% versus 6%, $p < 0.05$) were also lower in the rehabilitation group. The authors advised that their results be confirmed by a prospective RCT with both intention-to-treat analysis and longer follow-up.[56] The smaller RCT reported by Belardinelli et al (2001) did report a significantly lower event rate and decreased hospitalization. Overall the evidence is indicative of a net health benefit for this patient population.

While continued study is certainly encouraged, the evidence reviewed is considered adequate and overall supports the addition of Medicare coverage of cardiac rehabilitation for patients following PTCA.

Heart or Heart Lung Transplant

Heart and heart lung transplant patients must deal with a wide range of short and long term issues before and after transplantation. Since these transplants are relatively uncommon, no recent randomized controlled trials have been reported. Three systematic reviews and two recent case studies have indicated the benefits of cardiac rehabilitation and exercise in these patients. Although the studies have not specifically addressed survival, the evidence supports improvements in outcomes that are important and unique to these patients, such as walk distance, bone health, and quality of life. Given the limited number of these transplants, the evidence provided by case studies has been considered whereas in most other cases it would not. Although the number of studies are few, the circumstances surrounding heart and heart-lung transplantations have a considerable bearing on CMS's decision to provide coverage for cardiac rehabilitation for these patients.

While continued study is certainly encouraged, the evidence reviewed is considered adequate and overall supports the addition of Medicare coverage of cardiac rehabilitation for patients following heart or heart lung transplant.

Congestive Heart Failure

Congestive heart failure is a broad and often subjectively defined diagnosis. The New York Heart Association classification attempts to categorize the severity of symptoms but variability still exists in the type of heart failure, etiology and duration. This may create difficulties when attempting to identify the appropriate patients for inclusion into trials and the interpretation of results. In our review, there were 3 clinical trials on patients with NYHA class II or III with varying left ventricular ejection fraction criteria. Of the 3 studies, 2 (van den Berg-Emons, and Witham) did not find significant differences in their primary outcomes (more active lifestyle or improved quality of life, and 6 minute walk distance, respectively). Austin evaluated 5 outcomes (NYHA class, 6 minute walk distance, perceived exertion, quality of life and cost utility) and found promising results over baseline for these outcomes in the experimental group. However, the control group also had significant improvements in 2 of these outcomes (perceived exertion and quality of life). These findings were perplexing and may indicate some potential issues in the conduct of the trial or measurement of outcomes. There were also multiple comparisons and tests but adjustments were not made in the interpretation. The initial report by Jonsdottir suggested improvements in functional capacity, but the findings and data have not yet been published in a peer-reviewed journal so little weight can be given to this evidence at this time. Overall, the studies on CHF have enrolled a small number of patients and did not provide adequate data on the clinical outcomes of interest. None of these studies (or studies included in past analyses) were adequately designed with sufficient power to evaluate the effect of cardiac rehabilitation on mortality.

In addition to these trials, several systematic reviews were included in our analysis. All of the reviews (Ko, Delagardelle, Rees) noted the need for further evaluation. Ko and McKelvie concluded that, though the evidence was promising, confirmation was required from a large clinical trial. Delagardelle and Feiereisen's review focused on muscle wasting and strength training, rather than morbidity and mortality. Rees noted the small sample sizes and short follow-up durations as hindering the ability to draw definitive conclusions about the net health benefits for these patients. One meta-analysis (ExTraMATCH) suggested a mortality benefit, but as noted above, none of the trials included in this meta-analysis actually evaluated mortality as a primary outcome. Meta-analysis of outcomes that were not prespecified in the trials may be problematic. The ongoing HF-ACTION clinical trial was specifically designed to evaluate mortality with an estimated sample size of 3000 patients and should provide substantial, likely definitive, evidence on cardiac rehabilitation in patients with heart failure.

While there have been isolated promising results in functional status and quality of life, the findings of the trials have been mixed. This may be due in part to the heterogeneity of congestive heart failure and the cardiac rehabilitation programs themselves. At this time, the strength of the data does not reach the level of the evidence seen in the other indications. Until the results of HF-ACTION are available, the evidence is insufficient to determine the benefits of cardiac rehabilitation for patients with congestive heart failure.

B. Evaluating Previous Policy Requirements

Components of Cardiac Rehabilitation

The current policy does not specifically address the components of cardiac rehabilitation that CMS requires to be provided to beneficiaries as part of a comprehensive program. The evidence demonstrated that most benefit was shown in programs that included a comprehensive approach to cardiac rehabilitation. Therefore, CMS proposes identifying components of cardiac rehabilitation that must be part of a comprehensive program provided to beneficiaries.

The 2005 AHRQ report evaluated comprehensive cardiac rehabilitation programs and demonstrated that such programs provide patients with beneficial effects. Therefore, we propose requiring components similar to those identified in these programs be included in cardiac rehabilitation programs provided to Medicare beneficiaries. Consistent with the more detailed report by Balady, et al. (2000), we propose that programs include patient education, counseling on risk factor management, social and psychological support, nutritional counseling, and aerobic exercise. Previously, CMS only described cardiac rehabilitation as an exercise program for cardiac patients and did not include a discussion of the individual components that make up the program.

Physician Supervision

The OIG report specifically notes the need for CMS to address the confusion surrounding the physician supervision requirements.

To be covered as incident to physicians' services, the services and supplies must be furnished as an integral although incidental, part of the physician's professional service in the course of diagnosis or treatment of an illness or injury. The services and supplies must be furnished on a physician's order by hospital personnel and under a physician's supervision. This does not mean that each occasion of service by a nonphysician need also be the occasion of the actual rendition of a personal professional service by the physician. However, during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress, and where necessary, to change the treatment regimen. The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises; the hospital medical staff that supervises the services need not be in the same department as the ordering physician. However, if the services are furnished outside the hospital, they must be rendered under the direct personal supervision of a physician who is treating the patient. Direct supervision is defined at 42 C.F.R. §410.26(a)(2) (defined through cross reference to 42 C.F.R. §410.32(b)(3)(ii), or 42 C.F.R. §410.27(f). Other CMS manuals may provide further guidance (e.g., Medicare Beneficiary Manual §100-2, 6-20.4.1, 15-60.1 and 15-60.3).

Incident to

The OIG also recommended that CMS clarify the requirements regarding to which physician the services must be provided "incident to." The ordering physician is the "incident to" physician.

Cardiac rehabilitation services fall under the benefit category of "incident to" a physician's professional service which requires that services be performed under direct physician supervision. In the Social Security Act (§1861(r)) a physical therapist is not included in the definition of a physician therefore supervision by a physical therapist does not satisfy the supervision requirement. Physical therapists may only provide cardiac rehabilitation services when they are providing those services under the direct supervision of a physician as defined under §1861(r).

Number of Sessions and Frequency

Although the evidence is inconsistent, the majority of evidence reviewed in the technology assessments included studies allowing 36 cardiac rehabilitation sessions. The evidence regarding the number of sessions to be covered, when taken as a whole, did not militate in favor of changing the number of covered sessions from 36 sessions; as such the limit of 36 sessions will remain unchanged. However, delivering cardiac rehabilitation has changed over the years and many studies now allow patients to receive services twice per week instead of three times per week as outlined in the current NCD. To allow for greater flexibility in cardiac rehabilitation programs and to align more closely with the current evidence, CMS proposes lengthening the time allowed for beneficiaries to receive 36 sessions from 12 to 18 weeks. Since CMS did not identify evidence to remove contractor review and discretion over additional cardiac rehabilitation services, we propose that claims for services beyond 18 weeks should be reviewed by the contractors' medical consultants to determine if coverage should be extended but not exceed a total of 72 sessions for 36 weeks.

This proposal is a change from the current NCD which restricts 36 sessions to a maximum of 12 weeks and allows the contractor to extend coverage to a total of 72 sessions over a maximum of 24 weeks.

CMS proposes removing NCD language regarding specific exit criteria from a cardiac rehabilitation program. We were unable to find evidence to support these criteria and thus we propose to remove them.

Utilization Screens, ECG Rhythm Strips, Other Diagnostic and Therapeutic Services

The current NCD includes great details regarding the services surrounding cardiac rehabilitation. CMS proposes removing language specific to the use of ECG rhythm strips. Appropriate use of these services may be determined by the clinician and the Medicare local contractor if the contractor determines such a policy is necessary in their geographic area.

In the current NCD, there is extensive language regarding the use of psychotherapy, psychological testing, and physical and occupational therapy. We propose that discussion of those services in an NCD for cardiac rehabilitation is inappropriate as the language states that all other payment and coverage rules regarding those services apply regardless of the patient's participation in a cardiac rehabilitation program. Therefore, we propose to remove language regarding psychotherapy, psychological testing, and physical and occupational therapy.

IX. Proposed Conclusion

CMS proposes the following:

The evidence is adequate to conclude that cardiac rehabilitation is reasonable and necessary following acute myocardial infarction (AMI), coronary artery bypass graft (CABG), stable angina pectoris, heart valve repair/replacement, percutaneous transluminal coronary angioplasty (PTCA), and heart or heart lung transplant.

CMS has determined that the evidence is not adequate to conclude that cardiac rehabilitation is reasonable and necessary for congestive heart failure, and therefore we will not cover this indication.

CMS proposes revising the language in Manual 100-3 § 20.10 to read as follows:

A – Item/Service Description

Phase II cardiac rehabilitation, as described by the U.S. Public Health Service is a comprehensive, long-term program including medical evaluation, prescribed exercise, cardiac risk factor modification, education and counseling. Phase II refers to outpatient medically supervised programs that are typically initiated 1-3 weeks after hospital discharge and provide appropriate ECG monitoring.

B – Indications and Limitations of Coverage

Medicare coverage of cardiac rehabilitation programs are considered reasonable and necessary only for patients who (1) have a documented diagnosis of acute myocardial infarction within the preceding 12 months; or (2) have had coronary bypass surgery; or (3) have stable angina pectoris; or (4) have had heart valve repair/replacement; or (5) have had percutaneous transluminal coronary angioplasty (PTCA); or (6) have had heart or heart lung transplant.

C – Program Requirements

1.

Duration
Services provided in connection with a cardiac rehabilitation exercise program may be considered reasonable and necessary for up to 36 sessions without individual review by a contractor's medical consultant. Patients generally receive 2 to 3 sessions per week for 12 to 18 weeks. Claims for cardiac rehabilitation services beyond 18 weeks should be reviewed by the contractors' medical consultants to determine if coverage should be extended but not exceed a total of 72 sessions for 36 weeks.

2.

Components
Cardiac rehabilitation programs must be comprehensive and to be comprehensive they must include a medical evaluation, a program to modify cardiac risk factors (e.g., nutritional counseling), prescribed exercise, education and counseling.

3.

Facility
The facility must have available for immediate use the necessary cardio-pulmonary emergency diagnostic and therapeutic life saving equipment accepted by the medical community as medically necessary, e.g., oxygen, cardiopulmonary resuscitation equipment, or defibrillator.

4.

Staff
The program must be staffed by personnel necessary to conduct the program safely and effectively, who are trained in both basic and advanced life support techniques and in exercise therapy for coronary disease. The program must be under the direct supervision of a physician, as defined in 42 C.F.R. §410.26(a)(2) (defined through cross reference to 42 C.F.R. §410.32(b)(3)(ii), or 42 C.F.R. §410.27(f)).

Appendix A: General Methodological Principles of Study Design

CMS divides the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's risks and benefits.

The issues presented here represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has unique methodological aspects.

1. Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to help ensure adequate numbers of patients are enrolled to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias)
- Co-interventions or provision of care apart from the intervention under evaluation (confounding)
- Differential assessment of outcome (detection bias)
- Occurrence and reporting of patients who do not complete the study (attrition bias)

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study's selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess the evidence.

2. Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens, and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease, and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing, and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow -up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage decisions for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation), and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. The goal of our determination process is to assess net health outcomes, and we are interested in the results of changed patient management not just altered management. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

3. Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. For most determinations, CMS evaluates whether reported benefits translate into improved net health outcomes. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

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[1] Gordon et al (1997)

[2] Pashkow (1993)

[3] Forman et al (2000)

[4] Ades et al (2000)

[5] Wenger et al (1995)

[6] NHS 1998

[7] Jolliffe, *et al.* 2001

[8] Taylor, *et al.* 2004

[9] AHRQ 2005

[10] Witt, *et al.* 2004

[11] Blumenthal, *et al.* 2005

[12] Hedback, *et al.* 2001

[13] AHRQ, 2005.

[14] Ibid.

[15] Stewart, *et al.* 2003

[16] Stewart, *et al.* 2003

[17] Belardinelli, *et al.* 2001

[18] Dendale, *et al.* 2005

[19] Kavanagh, 2005.

[20] Ibid.

[21] Stewart, et al. 2003.

[22] Stewart, et al. 2003.

[23] Kavanagh, et al. 2003.

[24] Ibid.

[25] New York Heart Association Classification

Functional Capacity	Objective Assessment
Class I. Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	**A.** No objective evidence of cardiovascular disease.
Class II. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	**B.** Objective evidence of minimal cardiovascular disease.
Class III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.	**C.** Objective evidence of moderately severe cardiovascular disease.

Functional Capacity	Objective Assessment
Class IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	**D.** Objective evidence of severe cardiovascular disease.

[26] Jonsdottir, et al., 2005.

[27] Witham, et al., 2005.

[28] Austin, et al., 2005.

[29] Ibid.

[30] van den Berg-Emons, et al., 2004.

[31] Ibid.

[32] Ko, McKelvie, 2005.

[33] Keteyian, 2005.

[34] Cleland, et al., 2004.

[35] Ko, McKelvie, 2004.

[36] Delagardelle, Feiereisen, 2005.

[37] Reese, et al. 2004.

[38] ExTra MATCH, 2004.

[39] Ibid.

[40] Stewart, et al. 2003.

[41] Ibid.

[42] Wenger, *et al.* 1995

[43] Balady, *et al.* 2000

[44] Williams, *et al.* 2002

[45] Leon, *et al.* 2005

[46] NHS 1998

[47] Taylor, *et al.* 2004

[48] Thompson and Franklin 2004

[49] AHRQ 2005

[50] Wenger, *et al.* 1995

[51] Hedback, *et al.* 2001

[52] Taylor, *et al.* 2004

[53] AHRQ, 2005.

[54] Hotta 1991

[55] Hotta 1991

[56] Dendale, *et al.* 2005

Back to Top

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Back to Top